

REMARKS

On December 31, 2003, applicants submitted an amendment via facsimile to 703-308-8724, which is the facsimile number listed in the office action dated July 21, 2003. A copy of this amendment with the fax confirmation is enclosed. However, the U.S. Patent and Trademark Office reports that they have not received this amendment. As a result, applicant will assume that the December 31, 2003 amendment has not been entered and hereby submits the present amendment and Request for Continued Examination. The present amendment makes the same claim amendments and provides the same remarks as those set forth in the December 31, 2003 amendment.

Claims 1, 7, 9, 13, 15-29 and 33-34 were pending. Claims 7, 18-24 and 33-34 are cancelled. Claims 1, 9, 13, 15-17 and 25-29 are currently pending.

**The Claim Rejections Under 35 U.S.C. § 112 Should Be Withdrawn**

Claims 7, 18-24 and 33-34 have been rejected under 35 U.S.C. § 112, ¶ 1 as allegedly not being enabled.

The Office Action contends that the specification, while being enabling for a transgenic rat encoding a human NF-L gene promoter operative linked to SV40tsA58 gene, does not reasonably provide enablement for a neuronal cell line obtained from a transgenic rat . . . encoding C erb  $\beta$  2 gene or TGF  $\alpha$  gene operatively linked to a human NF-L promoter.

Applicant strongly disagrees.

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the art to make and use the claimed invention without undue experimentation. M.P.E.P. § 2164.01. “The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.” M.P.E.P. § 2164.01.

Moreover, “an extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance.” M.P.E.P. § 2164.06. Here, there is considerable direction and guidance in the specification on how to make and use the claimed invention and there is a high level of skill in the art.

The instant specification has guided one of skill in the art to the use of two preferred cell type specific promoters (NF-L gene and the MMTV promoter) and three preferred genes (SV40tsA58, C Erb  $\beta$  2, and TGF $\alpha$ ) to generate a transgenic rat, and cell lines derived therefrom, according to the claimed invention.

In particular, the specification provides examples of constructs and transgenic rats comprising constructs of a MMTV promoter coupled to a c-erbB-2 gene and a TGF $\alpha$  gene (*See* pages 48-61) and examples of constructs and transgenic rats comprising constructs of an NF-L promoter to a tsA58 gene (*See* pages 18, 20-21, 29-31, 33). The specification further provides examples where a tsA58 gene has been coupled to a MMTV promoter and rats comprising such constructs. (*See Spec. p. 18, 19, 24-29, 33*).

In view of these teachings, and the level of skill in the art, one of skill in the art would be guided and directed to make and use a transgenic rat comprising a human NF-L promoter operatively linked to a c-erbB-2 gene or a TGF $\alpha$  gene as provided for by the present invention, without undue experimentation.

Additionally, it is improper to issue a rejection solely based on the lack of workings example covering every embodiment of the invention. *See* M.P.E.P.

§ 2164.02. (“Compliance with the enablement requirement does not turn on whether an example is disclosed.” “The presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure . . . . To make a valid rejection, one must evaluate all the facts and evidence and state why one would not expect to be able to extrapolate the one example across the entire scope of the claims.”)

However, to secure issuance of the allowed claims, applicant hereby cancels claims 7, 18-24 and 33-34 from this application, without prejudice and reserves the right to continue prosecution of these claims.

In view of the foregoing, withdrawal of the enablement rejection and prompt allowance of allowed claims 1, 9 13, 15-17 and 25-29 is requested.

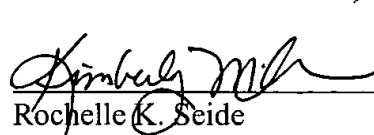
### CONCLUSION

In view of the foregoing, applicant submits that the application is condition for allowance and earnestly requests prompt allowance of the claims. Applicant hereby requests an extension of time to respond to the July 21, 2003 office action. A check in payment of the extension of time fee and the fee for Request for

Re-examination are enclosed. Applicant does not believe that any additional fees are required in connection with the submission of this paper. If any such fees are due in connection with the submission of this paper, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. Duplicate copies of this sheet are enclosed.

Respectfully submitted,  
BAKER BOTTS L.L.P.

By:

 January 21, 2004  
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